

*Joint B*

WHAT IS CLAIMED IS:

- 1           1. A timed-release compression-coated solid composition for oral  
2 administration, said composition comprising:  
3           a) a core tablet comprising a drug and a freely erodible filler, wherein said  
4 core tablet is capable of approximately 40 to approximately 90% erosion; and  
5           b) an outer layer, said outlayer is made from a hydrogel-forming polymer  
6 substance and a hydrophilic base, wherein said outer layer optionally contains a drug.
- 1           2. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the outer layer comprises a drug and wherein  
3 the outer layer essentially does not contain the same drug as the core tablet drug.
- 1           3. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein there is approximately 75 wt% or less of said  
3 drug, approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to  
4 approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to  
5 approximately 80 wt% hydrophilic base.
- 1           4. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more  
3 selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene  
4 glycol, sucrose, and lactulose. *or magent*
- 1           5. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more  
3 selected from the group consisting of malic acid, citric acid and tartaric acid.
- 1           6. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or  
3 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.
- 1           7. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the freely erodible filler for an acidic or neutral  
3 drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or  
4 lactulose.

1               8.     The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the hydrogel-forming polymer substance  
3 contains at least one type of polyethylene oxide.

1               9.     The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the hydrogel-forming polymer substance is 1 or  
3 2 or more having a viscosity-average molecular weight of 2,000,000 or higher and/or a  
4 viscosity in an aqueous 1% solution (25°C) of 1,000 cp or higher.

1               10.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the core tablet contains hydrogel-forming  
3 polymer substance.

1               11.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having  
3 solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.

1               12.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected  
3 from the group consisting of polyethylene glycol, sucrose, and lactulose.

1               13.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the hydrogel-forming polymer substance is at  
3 least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric  
4 oxide.

1               14.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein a drug is brought to be effectively released or  
3 absorbed in the lower digestive tract.

1               15.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein a drug is brought to be effective for  
3 chronopharmacotherapy.

1               16.    The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.

1               17. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein a drug has the effect of inhibiting metabolism  
3 by cytochrome P-450.

1               18. The timed-release compression-coated solid composition for oral  
2 administration according to claim 16, wherein the drug is metabolized by CYP3A4.

1               19. The timed-release compression-coated solid composition for oral  
2 administration according to claim 17, wherein the drug has the effect of inhibiting  
3 metabolism by CYP3A4.

1               20. The timed-release compression-coated solid composition for oral  
2 administration according to claim 1, wherein the drug is 4'-(2-methyl-1,4,5,6-  
3 tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

1               21. A method of timed release of a drug, whereby the composition in claim  
2 1 is orally administered.

1               22. A method for alleviating undesirable drug interaction between a drug  
2 and other drugs used concomitantly that employ the same route for drug absorption,  
3 distribution, metabolism or excretion *in vivo* in humans, whereby the composition in claim 1  
4 is orally administered.

1               23. A method of alleviating undesirable drug interaction with between a  
2 drug having the effect of inhibiting drug metabolism *in vivo* in humans and another drug  
3 according to claim 20 used concomitantly, whereby the composition in claim 1 is used.

1               24. In a hydrogel-forming compression-coated solid pharmaceutical  
2 preparation comprising: a core tablet containing drug and outer layer made from hydrogel-  
3 forming polymer substance and hydrophilic base, the improvement which comprises a timed-  
4 release compression-coated solid composition according to claim 1.

1               25. In a hydrogel-forming compression-coated solid pharmaceutical  
2 preparation comprising:

3                   a core tablet containing drug and outer layer made from hydrogel-forming  
4 polymer substance and hydrophilic base, the improvement which comprises a timed-release  
5 compression-coated solid composition for oral administration, said composition comprising:  
6                   (1) a drug and freely erodible filler are mixed with the core tablet;  
7                   (2) the percentage erosion of the core tablet is approximately 40 to  
8 approximately 90%; and  
9                   (3) the outer layer essentially does not contain the same drug as the above-  
10 mentioned drug.

1                   26.       The timed-release compression-coated solid composition for oral  
2 administration according to claim 25, wherein the drug is 4'-(2-methyl-1,4,5,6-  
3 tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.